



FDA Label Database Quickstart Manual

<http://ncsvmweb01.nctr.fda.gov/druglabel/>

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Overview

- The FDALabel Database is a free web-based application. It is implemented as a secure three-tier platform with an Oracle database. It can be found at the following webpage: <http://ncsvmweb01.nctr.fda.gov/druglabel/>
- Data is from the National Library of Medicine (NLM), hosted by DailyMed (<http://dailymed.nlm.nih.gov/dailymed/downloadLabels.cfm>). There is currently information for ~33,000 labels.
- The primary advantage of FDALabel is its ability to query the entire text of each drug label, within the product/generic name, or within a specific section (e.g., clinical pharmacology, adverse drug reactions, etc.).
- Other advanced searches include querying text within any combination of sections, dosage forms, SPL identifiers, document types, routes of administration, marketing categories, market status, and market start/end date.
- A user account can be created to save your searches and tag specific drug labels for later viewing.
- Currently, the database link is inside the FDA firewall; non-FDA users are not allowed to access the database.

Simple Search Interface Overview

Login to save searches or tags on specific labels

Drug Label Database - Logged in as hongfang [logout](#) [new advanced search](#) [new simple search](#)

Results limit

Results Type
label summaries

Results Limit
200

[Search](#)

Saved Searches

[Save Current Search](#)

Sorting: ☒ last-used first ☐ last-saved first

acute kidney failure
Oct 26, 2011 view load delete
Abacavir_generic
Oct 26, 2011 view load delete
HLA and abacavir
Nov 15, 2011 view load delete
acute liver failure
Oct 26, 2011 view load delete

Search entire drug label

Search for product or generic name

Full Text Query

Product Name
generic name contains text case sensitive

Tags
require all

[Advanced Search](#)

View saved tags; see Slide 13

Saved searches; see Slide 11

Example Basic Search

This basic search for "HLA and abacavir" queries every text field for all drug labels; furthermore, the entire text must include both "HLA" and "abacavir". Other standard boolean modifiers such as "or", "not", etc. are also supported. If no modifiers are used, all words must appear together.

This search returned 9 results (shown on [Slide 5](#)).

Click the "Search" button after entering your query parameters.

Drug Label Database - Logged in as hongfang [logout](#) [new advanced search](#) [new simple search](#)

Results Type
label summaries

Results Limit
200

Search

Save Current Search

Sorting: ☒ last-used first ☐ last-saved first

Warfarin
Oct 26, 2011 [view](#) [load](#) [delete](#)

acute kidney failure
Oct 26, 2011 [view](#) [load](#) [delete](#)

Full Text Query
HLA and abacavir

Product Name
generic name contains text ☐ case sensitive

Tags
 ☒ require all

[Advanced Search](#)

Viewing The Search Results Table

This table shows the 9 results from the query for "HLA and abacavir" from [Slide 4](#). (A separate search for "HLA" returns 109 results, and a separate search for "abacavir" returns 134 results).

If desired, the limit can be increased from the search page to see the total number of results

Save table to your computer (will save full query results even if limit is reached)

Returned all 9 results (limit not reached). [view search criteria](#) [save results](#)

Label Summaries

	NCTR SPL ID	PRODUCT GENERIC NAMES	MARKET CAT	DOSAGE FORMS	ORGANIZATION
1	4157	ABACAVIR SULFATE	NDA	TABLET, FILM COATED	STATE OF FLORIDA DOH CENTRAL PHARMAC
2	6188	ABACAVIR SULFATE AND LAMIVUDINE	NDA	TABLET, FILM COATED	PHYSICIANS TOTAL CARE INC
3	5823	ABACAVIR SULFATE AND LAMIVUDINE	NDA	TABLET, FILM COATED	STATE OF FLORIDA DOH CENTRAL PHARMAC
4	8413	ABACAVIR SULFATE AND LAMIVUDINE	NDA	TABLET, FILM COATED	GLAXOSMITHKLINE LLC
5	9282	ABACAVIR SULFATE AND LAMIVUDINE	NDA	TABLET, FILM COATED	VIIV HEALTHCARE COMPANY
6	13092	ABACAVIR SULFATE, LAMIVUDINE, AND ZIDOVUDINE	NDA	TABLET, FILM COATED	GLAXOSMITHKLINE LLC
7	13094	ABACAVIR SULFATE	NDA	SOLUTION;TABLET, FILM COATED	GLAXOSMITHKLINE LLC
8	13662	ABACAVIR SULFATE, LAMIVUDINE, AND ZIDOVUDINE	NDA	TABLET, FILM COATED	VIIV HEALTHCARE COMPANY
9	13170	ABACAVIR SULFATE	NDA	SOLUTION;TABLET, FILM COATED	VIIV HEALTHCARE COMPANY

Viewing a Specific Search Result

From the search results table, click on any table entry to view details; the drug label shown here is from the first result on [Slide 5](#) (SPL ID 4157).

Drug Label Database - Logged in as hongfang [logout](#) [new advanced search](#) [new simple search](#)

Tags

 ☐ make new tags public

[raw label html](#)

ZIAGEN - abacavir sulfate tablet, film coated
State of Florida DOH Central Pharmacy

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZIAGEN safely and effectively. See full prescribing information for ZIAGEN.

ZIAGEN[®] (abacavir sulfate) Tablets and Oral Solution

Initial U.S. Approval: 1998

WARNING: HYPERSENSITIVITY REACTIONS/LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY

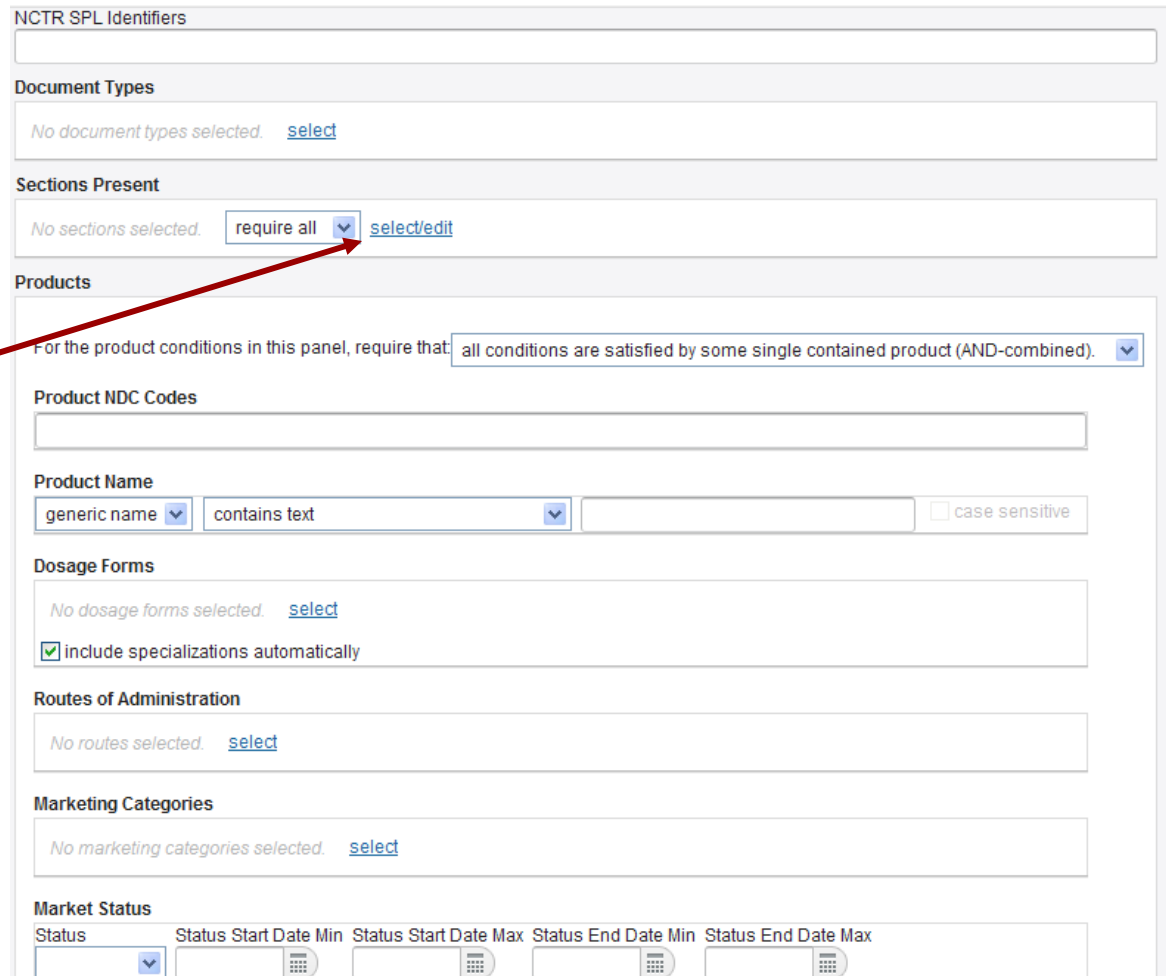
See full prescribing information for complete boxed warning.

- Serious and sometimes fatal hypersensitivity reactions have been associated with ZIAGEN (abacavir sulfate). (5.1)
- Hypersensitivity to abacavir is a multi-organ clinical syndrome. (5.1)
- Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir. (5.1)
- Discontinue ZIAGEN as soon as a hypersensitivity reaction is suspected. Regardless of HLA-B*5701 status, permanently discontinue ZIAGEN if hypersensitivity cannot be ruled out, even when other diagnoses are possible. (5.1)
- Following a hypersensitivity reaction to abacavir, NEVER restart ZIAGEN or any other abacavir-containing product. (5.1)
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues. (5.2)

Advanced Search Overview

Advanced searches include any combination of SPL identifiers, document types, sections, product/generic names, dosage forms, routes of administration, marketing categories, market status, and market start/end date.

e.g., Sections include “adverse drug reactions”, “boxed warning”, “overdosage”, “pregnancy”, etc.



The screenshot displays the Advanced Search interface with the following sections:

- NCTR SPL Identifiers**: A text input field.
- Document Types**: A text input field showing "No document types selected." with a [select](#) link.
- Sections Present**: A text input field showing "No sections selected." with a dropdown menu set to "require all" and a [select/edit](#) link. A red arrow points to this dropdown.
- Products**: A section with a dropdown menu set to "all conditions are satisfied by some single contained product (AND-combined)." and a [select/edit](#) link.
 - Product NDC Codes**: A text input field.
 - Product Name**: A text input field with a dropdown menu set to "generic name", a dropdown menu set to "contains text", and a ☐ case sensitive checkbox.
 - Dosage Forms**: A text input field showing "No dosage forms selected." with a [select](#) link, and a checked checkbox for "include specializations automatically".
 - Routes of Administration**: A text input field showing "No routes selected." with a [select](#) link.
 - Marketing Categories**: A text input field showing "No marketing categories selected." with a [select](#) link.
 - Market Status**: A section with a dropdown menu set to "Status" and five date input fields labeled "Status Start Date Min", "Status Start Date Max", "Status End Date Min", and "Status End Date Max".

Example Advanced Search: Sections

In the search shown here, resulting drug labels must contain the phrase “impaired kidney function” in the “Clinical Pharmacology” section, and also have a “Boxed Warning” section.

This search returned 3 results, shown below.

The screenshot shows the 'Advanced Search' interface. The 'Sections Present' section is highlighted with a red oval. It contains two criteria: 'require all' (selected) and 'select/edit'. Below these are two boxes: 'BOXED WARNING containing' and 'CLINICAL PHARMACOLOGY containing impaired kidney function'. The 'Full Text Query' field is empty. The 'Tags' section has a dropdown menu and a '+ require all' checkbox. The 'NCTR SPL Identifiers' field is empty. The 'Document Types' section shows 'No document types selected.' with a 'select' link. The 'Products' section has a dropdown for 'For the product conditions in this panel, require that' set to 'all conditions are satisfied by some single contained product (AND-combined)'. The 'Product NDC Codes' field is empty. The 'Product Name' section has a dropdown for 'generic name' and a dropdown for 'contains text'.

Returned all 3 results (limit not reached). [view search criteria](#) [save results](#)

Label Summaries

	NCTR SPL ID	PRODUCT GENERIC NAMES	DOCUMENT TYPE	MARKET DATES	MARKET CAT	DOSAGE FORMS
1	211	ZALCITABINE	HUMAN PRESCRIPTION DRUG LABEL			TABLET, FILM COATED
2	9924	TOREMIFENE CITRATE	HUMAN PRESCRIPTION DRUG LABEL	1997/06/30-	NDA	TABLET
3	13447	PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE	HUMAN PRESCRIPTION DRUG LABEL	1953/05/18-	NDA	INJECTION, SUSPENSION

Example Advanced Search: Combination of Generic Name and Dosage Form

This search queries the database for drugs with the “Hydrocodone” in the generic name and appear in the form of capsules.

This search returned 6 results, shown below (replacing Capsule with Tablet, the more common form of Hydrocodone, returns 181 results).

Products

For the product conditions in this panel, require that:

Product NDC Codes

Product Name

generic name Hydrocodone ☐ case sensitive

Dosage Forms

CAPSULE

☒ include specializations automatically

Routes of Administration

No routes selected.

Marketing Categories

No marketing categories selected.

Market Status

Status

Returned all 6 results (limit not reached). [view search criteria](#) [save results](#)

Label Summaries

	NCTR SPL ID	PRODUCT GENERIC NAMES	DOSAGE FORMS	ORGANIZATION
1	117	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	CAPSULE	MIKART INC
2	572	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	CAPSULE	MALLINCKRODT INC
3	713	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	CAPSULE	MIKART INC
4	717	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	CAPSULE	MIKART INC
5	739	HYDROCODONE BITARTRATE AND ACETAMINOPHEN	CAPSULE	MIKART INC
6	5781	HYDROCODONE POLISTIREX AND CHLORPHENIRAMINE POLISTIREX	CAPSULE, EXTENDED RELEASE	MALLINCKRODT INC

The “include specializations” checkbox added this result

Example Advanced Search: Market Status and Dates

The search shown here queries for drugs that were introduced between in either 2009 or 2010.

This search returned 11266 results, the first few of which are shown below.

Products

For the product conditions in this panel, require that: all conditions are satisfied by some single contained product (AND-combined).

Product NDC Codes

Product Name

generic name contains text case sensitive

Dosage Forms

No dosage forms selected. [select](#)

☒ include specializations automatically

Routes of Administration

No routes selected. [select](#)

Marketing Categories

No marketing categories selected. [select](#)

Market Status

Status Status Start Date Min Status Start Date Max

active 1/1/09 12/31/10

Returned all 11266 results (limit not reached). [view search criteria](#) [save results](#)

Label Summaries

	NCTR SPL ID	PRODUCT GENERIC NAMES	DOCUMENT TYPE	MARKET DATES	MARKET CAT	DOSAGE FORMS
1	1532	ALBUMIN HUMAN	HUMAN PRESCRIPTION DRUG LABEL	2009/01/06-	BLA	SOLUTION
2	1551	ALBUMIN HUMAN	HUMAN PRESCRIPTION DRUG LABEL	2009/01/06-	BLA	SOLUTION
3	1558	ALBUMIN HUMAN	HUMAN PRESCRIPTION DRUG LABEL	2009/01/06-	BLA	SOLUTION
4	1645	LORAZEPAM	HUMAN PRESCRIPTION DRUG LABEL	2009/04/01-	ANDA	SOLUTION, CONCI
5	1646	HYDRALAZINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG LABEL	2009/06/01-	ANDA	TABLET
6	1747	MEPROBAMATE	HUMAN PRESCRIPTION DRUG LABEL	2009/06/24-	ANDA	TABLET

Saving and Using Saved Searches

From the main page, all saved searches can be found on the left. Clicking "load" will fill in the search fields with the appropriate parameters. Clicking "view" will give a summary of these parameters.

You must be logged in to save searches.

Drug Label Database - Logged in as hongfang [logout](#) [new advanced search](#) [new simple search](#)

Results Type
label summaries ▼

Results Limit
200

[Search](#)

Saved Searches

[Save Current Search](#)

Sorting: ☒ last-used first ☐ last-saved first

Warfarin

Oct 26, 2011 [view](#) [load](#) [delete](#)

acute kidney failure

Oct 26, 2011 [view](#) [load](#) [delete](#)

Full Text Query

acute liver failure

Product Name

generic name ▼

contains text ▼

☐ case sensitive

Tags

+

☒ require all

[Advanced Search](#)

Saves currently entered search (full text query for "acute liver failure" in this case)

Saved searches

Saving Tags

While viewing a drug label, type in a name and click the + button to save a tag to easily access this label in the future. All users will be able to see the tag if the “make public” checkbox is checked.

You must be logged in to save tags.

Tags

☐ make new tags public

[raw label.html](#)

COMBIVIR - lamivudine and zidovudine tablet, film coated
Stat Rx USA

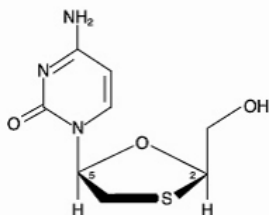
COMBIVIR (lamivudine and zidovudine) tablet, film coated

11 DESCRIPTION

COMBIVIR: COMBIVIR Tablets are combination tablets containing lamivudine and zidovudine. Lamivudine (EPIVIR) and zidovudine (RETROVIR, azidothymidine, AZT, or ZDV) are synthetic nucleoside analogues with activity against HIV-1.

COMBIVIR Tablets are for oral administration. Each film-coated tablet contains 150 mg of lamivudine, 300 mg of zidovudine, and the inactive ingredients colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, and titanium dioxide.

Lamivudine: The chemical name of lamivudine is (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one. Lamivudine is the (-)-enantiomer of a dideoxy analogue of cytidine. Lamivudine has also been referred to as (-)-2',3'-dideoxy, 3'-thiacytidine. It has a molecular formula of $C_8H_{11}N_3O_3S$ and a molecular weight of 229.3. It has the following structural formula:



Using Tags

To view all drug labels with either your user-assigned tag or a public tag, use the drop-down menu to select the desired tag and click the "Search" button. Tags are combined with AND if the checkbox is checked, and combined with OR otherwise.

See [Slide 12](#) to learn how to save tags.

Drug Label Database - Logged in as hongfang [logout](#) [new advanced search](#) [new simple search](#)

The screenshot displays the 'Drug Label Database' search interface. On the left, there's a sidebar with 'Results Type' set to 'label summaries' and 'Results Limit' set to '200'. Below this is a 'Search' button. Under 'Saved Searches', there's a 'Save Current Search' link and a sorting option set to 'last-used first'. A list of saved searches is shown, including 'acute liver failure' dated 'Oct 26, 2011' with 'view', 'load', and 'delete' links. The main search area has a 'Full Text Query' input field. Below it, the 'Product Name' section has a dropdown set to 'generic name' and a search type dropdown set to 'contains text', followed by a 'case sensitive' checkbox. The 'Tags' section shows a tag selection interface with a dropdown menu open, displaying 'TEST PUBLIC' and 'warfarin'. A red arrow points to the 'warfarin' tag with the text 'Selected tag(s)'. Another red arrow points to the dropdown menu with the text 'User's and public tags'. A 'require all' checkbox is checked. A link for 'Advanced Search' is also visible.

Results Type
label summaries

Results Limit
200

Search

Saved Searches

[Save Current Search](#)

Sorting: ☒ last-used first ☐ last-saved first

acute liver failure
Oct 26, 2011 [view](#) [load](#) [delete](#)

Full Text Query

Product Name
generic name contains text case sensitive

Tags

TEST PUBLIC
warfarin

require all

warfarin

[Advanced Search](#)

Selected tag(s)

User's and public tags



In Development

- Search by active ingredients
- Possible automatic database updates (from NLM)
- Interface enhancements
- Performance improvements



Questions?

- To submit ideas or requests, Dr. Weida Tong and Dr. Hong Fang at NCTR (weida.tong@fda.hhs.gov and hong.fang@fda.hhs.gov)
- Technical support, suggestions, and bug reports should be sent to stephen.harris@fda.hhs.gov and hong.fang@fda.hhs.gov
- General questions can be sent to NCTRBioinformaticsSupport@fda.hhs.gov